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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,566	09/10/2003	Christophe Dupont	2756.001	4677

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,566	DUPONT ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12,14-19 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 June 2009 has been entered.

Claim Rejections - 35 USC § 112(New Matter Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term " solely" in line 14 of instant claim 1 is unclear in view of the scope and content of the claim. The limitation drawn to an active substance bound to the support within the chamber solely by electrostatic forces was not explained and/or described in the specification in such a way that the limitation drawn to interaction solely by electrostatic forces is enabled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6-12, 14-19 and 21-23 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-2 and 5-13 of copending Application No. 11/411531 (USPN '531, hereinafter). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: USPN '531 discloses a **patch** which is **electrically charged**. **A predetermined amount of a powdered biologically active substance** is applied. Accordingly,

an **adhesive seal against the patient's skin is achieved via the configuration of the patch** also forming a **moisture-retaining chamber**.

The other limitations of USPN '531 extend to the **patch being disk-shaped** and **comprising a label removably coupled to the adhesive**. Further, USPN '531 discloses a patch in claim 13 **specifically containing an allergen as the biologically active substance**.

Claims 1-4, 6-12, and 14 -19 and 21-23 of this instant application 10/659566 essentially teach the same invention with the exception of the plurality of variable configurations of different shapes of the fabric incorporated to make the patch mesh. Instead, 10/659566 teach a plurality and increasing amount of allergens that may be applied to the patch.

The current application teaches a **skin patch** that **is pre-loaded with a pre-selected amount of a biologically active substance in the form of individualized or agglomerated particles.** These **particles are held into place by electrostatic forces** in a **hermetically sealed** skin patch. The patch further comprises a **label removably coupled to the adhesive**. The patch may be **disk-shaped and contain an allergen.**

The applications differ in the configuration of the patch design. USPN '531 discloses that the patch is electrically charged. The current application does not support and/or suggest this specific limitation. However, essentially, the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Still further, the limitation of claim 19 drawn to different species of supports upon which the particles are to be agglomerated via electrostatic forces is invariably supported and suggested in the patch material of USPN '531 which are specifically designed to harbor electrostatic forces.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-12, and 14-19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osbourn et al. (USPN 3,212,495) in view of Van Dyke et al. (USPN 6,316,598 B1).

Osbourn et al. teach a "plurality of patch test articles" on a strip of adhesive material (FIGURE 4 col. 3, lines 42-46). Thus, the limitation in claim 6 drawn to regions separated by adhesive regions is made obvious.

Osbourn et al. teaches circular pads surrounded by adhesive regions. The overall strip comprising a plurality of patches as shown in Figure 4 is rectangular. Circular patches have been art-known and reasonably constitute a simple design choice. The use of labels on adhesive layers as found in claim 12 is well-known in the art (col. 3, item 17). Thus, Osbourn et al. teaches embodiments drawn to patches for the purpose of doing skin sensitivity testing.

Further, Osbourn et al. teach an invention related to skin patches to determine the sensitivity to various substances. Osbourn does not teach keratin *per se* but the motivation is reasonably present in view of the optimizations of Osbourn drawn to various substances to be tested for sensitization.

Van Dyke et al. teach the preparation of an antigen (keratin) as a powder for putting on a patch.

Van Dyke et al. teach [a] hydratable, highly absorbent keratin **solid fiber or powder** capable of absorbing a large weight excess of water may be produced by partially oxidizing hair keratin disulfide bonds to sulfonic acid residues and reacting the sulfonic acid residues with a cation. The neutralized suspension can be filtered, washed, and **dried** leaving keratin solid which can be shredded into fibers and further ground into powder. Addition of water to the solid produces a hydrogel. **The powder or hydrogel may be useful as an absorbent material, as a therapeutic for skin, or as an excipient.** Another use for the hydrogel is as a biocompatible viscoelastic filler for implant applications (abstract only).

The powdered keratin is inherently antigenic, or can serve as a delivery vehicle for other added excipients or drugs to be used in the skin sensitivity tests of Osbourn et al.

Van Dyke et al. teach another application where the keratin can be used in powder, fiber, or film form in order to provide a moist, benign environment against the skin for drug release. (col. 13, lines 42-46)

Van Dyke et al. further teach the release rate of a keratin excipient preparation [which] is determined by the rate at which water is absorbed and the keratin solid disintegrates (col. 10, lines 44-47).

Van Dyke et al. specifically teach dried keratin that can be directly ground into a powder using a mortar and pestle *inter alia* into particles (col. 12, lines 44-49).

Van Dyke et al. teach a keratin adsorbent material that may be used as a wound dressing, may be stored as a dry powder, can be formulated in absorbent powder (hence, hydrophilicity

and hydrophobicity) and the fibers of keratin can be woven together to reasonably form an occlusive dressing (column 3, lines 58-67).

The embodiments of Van Dyke reasonably provide for the formulation of powdered biologically active substance, keratin, which is also a protein and considered to be antigenic, without the use of solvents or carriers. Keratin may be administered directly as a woven fiber matrix or as a powder impregnated in a woven layer of a product. Embodiments of the invention of Van Dyke et al. do not teach the use of any liquid carrier, only the powder form of keratin is provided to the surface of the substrate dressing. Therefore, the sole force holding the powder on the surface is electrostatic.

In the alternative, the invention of Van Dyke et al. is disclosed in an embodiment that is drawn to being used as a wound dressing ***that includes a hydratable keratin*** solid. Hydratable keratin is indicated as a coating on the layer of a product, associated with a non-woven layer of a product (which could reasonably be extended to the patch of current invention), or even impregnated into a layer of a product or contained in an absorbent core (col. 7, lines 29-37).

Van Dyke et al. teach a method of making a hydratable keratin solid (col. 5, lines 26-41).

The one of ordinary skill would readily recognize that keratin could reasonably be classified as an allergen based upon art-known and well-established documentation drawn to animal product allergy problems.

Van Dyke et al. does not teach the intended use of keratin in as far as the said dried keratin powder being incorporated/impregnated in a dry patch in order to test for skin sensitization in humans.

Further, with regard to the allergens of claim 23, the keratin of Van Dyke et al. is obvious in view of the citation in the instant specification page 2, lines 10-26 and specifically line 21 drawn to animal hair and feathers (the essential material of keratin).

Van Dyke et al. teach the scope and content of the prior art in as far as the propensity to employ a dry bioactive substance such as keratin onto a plain patch or pad would apply. Keratin, itself according to Van Dyke et al. may also act as the woven fiber matrix (formed into a pad/patch presumably), powdered, and impregnated in a woven layer of a product which reasonably extends to a patch as disclosed in the current invention. Osborne et al. provides further motivation to combine with teachings drawn specifically to the limitation in claim 6.

It would have been *prima facie* obvious to the one of skill to use the powdered keratin formulated from animal hair as taught by Van Dyke et al. on the patch system as shown by Osbourn et al. for the purposes of using keratin in an antigenic sensitivity test. Alternatively, the powdered keratin of Van Dyke et al. can serve as a water absorbing powder for the release of other agents incorporated into the patch. See Van Dyke (col. 13, lines 42-46). Therefore, the use of the powdered keratin of Van Dyke et al. in the sensitivity test patches of Osbourn et al. would have been obvious to one of ordinary skill in the art. Any differences between the prior art and the claims at issue are directed to specific limitations attributed to claims 6-12 drawn to shapes, sizes, specific manipulated/engineered configurations (*label removably coupled* in claim 12) would have been obvious variations on patch design but not function, and therefore would impart no patentable distinction over the prior art.

Note: Under 37 CFR 1.121 current claims 1-4, 6-18 and 19-22 renumbering specifically by renumbering claims 21-23 as 20-22 because applicants' inadvertently failed to disclose instant claim 20 in the current claim set (6/9/2009). Applicants' are advised that there are only 22 claims inclusive of cancelled and withdrawn claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617